

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

81-051/S-005

Trade Name: Lortab Elixir

Generic Name: Hydrocodone Bitartrate and
Acetaminophen Elixir; 7.5mg/500mg per
15 mL

Sponsor: Mikart, Inc.

Approval Date: July 25, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

81-051/S-005

CONTENTS

Reviews / Information Included in this ANDA Review.

Approval Letter(s)	X
Tentative Approval Letter(s)	
Final Printed Labeling	
CSO Labeling Review(s)	
Medical Officer Review(s)	
Chemistry Review(s)	X
Microbiology Review(s)	
Bioequivalence Review(s)	
Administrative Document(s)	
Correspondence	X

**CENTER FOR DRUG
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RESEARCH**

APPLICATION NUMBER:

81-051/S-005

APPROVAL LETTER

ANDA 81-051/S-005 (7.5 mg/500 mg per 15 mL) ✓
81-226/S-001 (5 mg/50 mg per 15 mL)
89-557/S-001 (5 mg/50 mg per 15 mL)

Mikart, Inc.
Attention: Cerie B. McDonald
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318-2112

JUL 25 1995

Dear Madam:

This is in reference to your supplemental new drug application dated January 25, 1995, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Hydrocodone Bitartrate and Acetaminophen Elixir.

The supplemental application provides for _____

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

1/1

ISI

7/25/95

Florence S. Fang
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

**CENTER FOR DRUG
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RESEARCH**

APPLICATION NUMBER:

81-051/S-005

CHEMISTRY REVIEW(S)

ANDA 81-051/S-005 (7.5 mg/500 mg per 15 mL, 1st review)
81-226/S-001 (5 mg/50 mg per 15 mL, 1st review)
89-557/S-001 (5 mg/50 mg per 15 mL, 1st review)

NAME AND ADDRESS OF APPLICANT:

Mikart, Inc.
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318-2112

PURPOSE OF AMENDMENT/SUPPLEMENT

81-051/S-005, 81-226/S-001 & 89-557/S-001:
Control revision -

DATE(S) OF SUBMISSION(S)

Firm: 1/25/95 - Original supplement, all three.

PHARMACOLOGICAL CATEGORY

Relief of moderate to
moderately severe pain

TRADE NAME

None

NONPROPRIETARY NAME

Hydrocodone Bitartrate
and Acetaminophen

DOSAGE FORM

Elixir

POTENCY

7.5 mg/500 mg per 15 mL
5 mg/500 mg per 15 mL

RX OR OTC

R

SAMPLES

N/A

RELATED IND/NDA/DMF

N/A

STERILIZATION

N/A

LABELING - N/A

BIOEQUIVALENCY STATUS - N/A

ESTABLISHMENT INSPECTION - N/A

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS - N/A

Brought forward from previous review.

[]
Orig. Appvd. 8/28/92 (81-051), 10/27/92 (81-226) &
4/29/92 (89-557)

Brought forward from previous review.

[]
Orig. Appvd. 8/28/92 (81-051), 10/27/92 (81-226) &
4/29/92 (89-557)

Redacted

4

pages of trade

secret and /or

confidential

commercial

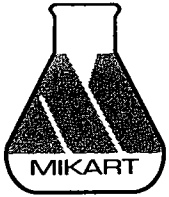
information

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APPLICATION NUMBER:

81-051/S-005

CORRESPONDENCE



MIKART, INC.

PHARMACEUTICAL MANUFACTURERS

January 25, 1995

Mr. Douglas L. Sporn, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II (MPN II)
Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA NO.

REF. NO.

5005

NDA SUPPL FOR

Concluded Rev

RE: ANDA 81-051 Hydrocodone Bitartrate and Acetaminophen Elixir
(7.5 mg/500 mg per 15 mL)
Supplement to an approved application

Dear Mr. Sporn,

Mikart would like to supplement the above application to _____
in Hydrocodone Bitartrate and Acetaminophen Elixir (7.5 mg/500 mg
per 15 mL). The information contained herewith is submitted as
part of a multiple supplement.

The details of this supplement can be found in the following
pages. Please let us know if you require any further informa-
tion. Thank you for your cooperation in the review of this
material.

Sincerely,

Cerie B. McDonald
Executive Vice-President

CBM/sw

RECEIVED

FEB 03 1995

GENERIC DRUGS